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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,648	09/24/2001	Robert F. Sak	004122.00006	6515
22907	7590	06/01/2005		
BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001			EXAMINER SZMAL, BRIAN SCOTT	
			ART UNIT 3736	PAPER NUMBER

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/960,648

Applicant(s)

SAK, ROBERT F.

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-29 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5 and 15 is/are rejected.
- 7) ☒ Claim(s) 3 and 6-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4, 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (1,867,624) in view of Leet et al (5,795,309).

Hoffman discloses a biopsy device and further discloses an insertion tube (22); an introduction guide member (24), the introduction guide member (24) extending beyond an end of the tube (22); and a sampler, the sampler comprising a collecting member (30, 37, 47).

Hoffman however fails to disclose a cervical sampler with a forward end including a holder for mating with the sample collecting member and a rear end for grasping by an operator; the rear end of the cervical sampler includes a handle; the holder mates with the sampling collecting member such that the sample collecting member rotates when the handle is rotated; and the sample collecting member includes a cervical sampling brush.

Leet et al disclose a cervical tissue sampling device and further disclose a cervical sampler with a forward end including a holder for mating with the sample collecting member and a rear end (26) for grasping by an operator; the rear end of the cervical sampler includes a handle; the holder mates with the sampling collecting member such

that the sample collecting member rotates when the handle is rotated; and the sample collecting member includes a cervical sampling brush (28). See Figure 1.

Since both Hoffman and Leet et al disclose biopsy devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hoffman to include the use of a cervical sampler, as per the teachings of Leet et al, since it would provide a means of obtaining cervical samples from a patient.

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (1,867,624) and Leet et al (5,795,309) as applied to claim 1 above, and further in view of Marx (4,369,022).

Hoffman and Leet et al, as discussed above, disclose biopsy devices but fail to disclose an insertion position indicator located along a length of the insertion tube.

Marx discloses an endometrial tissue sampling device and further disclose an insertion position indicator located along a length of the insertion tube. See Column 2, line 1.

Since Hoffman, Leet et al and Marx disclose biopsy devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Hoffman and Leet et al to include the use of a position indicator, as per the teachings of Marx, since it would provide a means to the operator to determine the position of the distal end of the biopsy device within the patient.

***Allowable Subject Matter***

Art Unit: 3736

4. Claims 3 and 6-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter: Claims 20-29 are allowable since no prior art could be found teaching or suggesting inserting an introduction guide member into a vaginal insertion tube so that a portion of the introduction guide member extends outwardly from a forward end of the vaginal insertion tube and withdrawing the introduction guide member from the vaginal insertion tube, as claimed in Claim 20; and a forward end of the cervical sampler including a holder with hemispherical projections for mating with the sample collecting member, as claimed in Claim 29.

#### ***Terminal Disclaimer***

6. The terminal disclaimer filed on March 2, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,302,853 B1 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1, 2, 4, 5 and 15 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 3736


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BS



MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700